UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
v.	)	No.: 3:19-CR-60-TAV-DCP
	)	
SHARON NAYLOR,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

All pretrial motions in this case have been referred to the undersigned pursuant to 28 U.S.C. § 636(b) for disposition or recommendation as appropriate. This case is before the Court on the Defendant's Motion to Limit Expert Medical Opinion [Doc. 60], asking to restrict the testimony of the Government's expert, Dr. Timothy Munzing, due to his faulty methodology. Defendant asserts that of the 1,488 patients treated at LaFollette Wellness Center (LWC), Dr. Munzing reviewed nine patient files, which were hand-picked by the Government. Defendant argues that because these nine files are not a representative sample, Dr. Munzing's proposed expert testimony on the general prescribing practices of nurse practitioner Alicia Taylor and Dr. Henry Babenco and on the general standard of care at LWC is both unreliable and unfairly prejudicial.

As agreed by the parties, the Court finds Dr. Munzing may not extrapolate from the nine patient files he reviewed to the general patient care or prescribing practices of LWC or its medical staff. The Court also finds that Dr. Munzing may not opine on patterns in the prescribing data or the data from the Controlled Substance Monitoring Database. While Dr. Munzing may testify about the level of care provided to patients whose files or care are the subject of testimony at trial, the Government must provide notice of these patients four weeks before trial.

I. BACKGROUND

The Indictment charges that Defendant Sharon Naylor was an advanced practice registered nurse and the owner of LWC, a pain management clinic [Doc. 1 ¶¶ 6, 8]. Defendant Henry Babenco, a medical doctor, was the supervising physician at LWC; Defendant Alicia Taylor was a physician's assistant at LWC, supervised by Dr. Babenco; and Defendant Gregory Madron was the manager at LWC [*Id.* at ¶¶ 7, 9–10]. Defendant Naylor is charged with conspiring with Defendants Babenco, Taylor, Madron, and unnamed others to distribute and dispense opioids outside the scope of professional practice and without legitimate medical purpose from May 2016 to December 2018 (Count One) [*Id.* at ¶ 12]. Defendant Naylor is also charged with seven counts of distributing opioids outside the usual course of professional practice and without a legitimate medical purpose (Counts Two–Eight) and with money laundering (Count Nine) [*Id.* at ¶ 14 & p. 5].

On March 13, 2020, the Government gave notice of its intent to present the expert testimony of Dr. Timothy Munzing in its case-in-chief [Doc. 33]. The Government summarizes Dr. Munzing's testimony as follows:

> Dr. Munzing is expected to testify about the usual course of the professional practice of medicine, including the importance of reaching the correct diagnosis and offering the correct individual treatment for each patient. In addition to the details of quality clinical care, Dr. Munzing will also discuss appropriate prescribing practices and the signs of potential addiction.
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> Dr. Munzing conducted a file review for the patients listed in Counts 2 through 8, as well as other patients of the Lafollette Wellness Center during the timeframe of the indictment. The government expects Dr. Munzing to testify specifically about the following:
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> ■ The usual course of professional practice for physician assistants, nurses, and doctors, including the importance of offering correct treatment through individualized quality clinical care;

> ■ Appropriate opioid prescribing practices, methods to monitor pain patients for indicators of drug abuse and/or diversion, and the signs of potential opioid addiction in patients;
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> ■ His observations regarding the general prescribing practices of Alicia Taylor and Henry Babenco, based upon a review of their patient files;
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> ■ His opinion that both the specific prescriptions and the general prescribing practices at issue were outside the scope of professional medical practice, and without a legitimate medical purpose;
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> ■ The specific troubling findings from his patient file reviews which formed the basis of the opinions listed above. Such findings are detailed in Dr. Munzing's report and included, for example: poor recordkeeping, ignored aberrancies in urine drug testing, extremely high opioid dosing/MME equivalents, dangerous prescription drug combinations, and failure to pursue safer alternative treatments.

[*Id.* at 2–3]. Of these five points, Defendant raises concerns about the third and fourth.

On August 2, 2021, Defendant Naylor moved to limit the expert testimony of Dr. Munzing, arguing that it is unreliable [Doc. 60]. Defendant objects to the lack of any scientific methodology for selecting the nine patient files. She argues that as a result, the Court should not permit Dr. Munzing to testify about the standard of care of Taylor and Babenco or the clinic as a whole. Alternatively, Defendant Naylor contends that the unfair prejudice from this proposed testimony substantially outweighs its minimal probative value.

The Government responded in opposition [Doc. 65], arguing that Dr. Munzing's testimony will be based on the entirety of the evidence, including data, hypotheticals, and other evidence presented at trial.

The parties appeared by video for a motion hearing on these issues on September 16, 2021. Assistant United States Attorneys Emily E. Petro and Anne-Marie Svolto appeared on behalf of the Government. Attorneys Robert R. Kurtz, William Johnson, and Daniel Ripper represented

Defendant Naylor, who was excused from this hearing. After hearing the arguments of the parties, the Court took the motion under advisement.[1]

At the Court's request, and following a motion to continue the trial until after the Supreme Court's ruling on issues[2] relating to the standard of care, the parties submitted a Joint Supplement as to Status of Pending Motions [Doc. 71]. In their supplement, they assert that "to the extent the Supreme Court decides issues relating to the standard(s) of proof regarding medical experts, such issues could be addressed appropriately through respective motions *in limine*" [*Id.* at 1]. Thus, the parties presented no additional argument on Dr. Munzing's proposed testimony and agreed the motion is ripe for determination [*Id.*].

II. ANALYSIS

"Unlike an ordinary witness . . . an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579, 592 (1993) (citing Fed. R. Evid. 701–703). Federal Rule of Evidence 702 governs the admissibility of expert testimony:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise, if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue,
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> (b) the testimony is based on sufficient facts or data;

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[1] The Court also heard argument on Defendant's Motion to Exclude Testimony of Nurse Consultant Natalie Seabolt [Doc. 62]. The parties subsequently agreed this motion is moot because the Government no longer intends to call Nurse Seabolt as a witness [*see* Doc. 72].

[2] On June 27, 2022, the Supreme Court decided *Ruan v. United States*, 142 S. Ct. 2370 (2022), on the standard of care for medical providers prosecuted under the Controlled Substances Act. Defendant Naylor's trial is set for November 8, 2022.

> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

The party offering the expert, here the Government, must show by a preponderance of the evidence that the proposed expert testimony satisfies the requirements of Rule 702. Fed. R. Evid. 702, advisory committee's note to 2000 amendment; *see also Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir.) (citing *Daubert*, 509 U.S. at 592 n.10), *cert. denied*, 534 U.S. 822 (2001).

In assessing the propriety of expert testimony, the Court examines whether the expert is qualified and whether the testimony is reliable and will help the jury determine a fact at issue. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517 528-29 (6th Cir. 2008); *United States v. Stapleton*, No. 12–11–ART–(1), -(2), -(4), 2013 WL 5966122, at *2 (E.D. Ky Nov. 8, 2013). The trial judge must act as a gatekeeper, admitting only that expert testimony that is relevant and reliable. *Daubert*, 509 U.S. at 589, 597. As to scientific knowledge, the court must initially determine whether the reasoning or methodology used is scientifically valid and is properly applied to the facts at issue in the trial. *Id.* at 589. In *Daubert,* the Supreme Court provided several key considerations to guide courts in their gatekeeping role: (1) Can or has the scientific knowledge been tested, (2) Has the given theory or technique been published or the subject of peer review, (3) Does a known error rate exist, and (4) Does the theory enjoy acceptance in the particular field. *Id.* at 593-94.

Although *Daubert* focused on the admissibility of scientific expert opinions, the trial court's gatekeeping function applies to all expert testimony, including that based upon specialized or technical, as opposed to scientific, knowledge. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137,

147-48 (1999); *Berry v. City of Detroit*, 25 F.3d 1342, 1350 (6th Cir. 1994). The trial court's objective "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. Although the general principles established in *Daubert* apply to all experts, the enumerated considerations may or may not apply to a particular non-scientific expert. *Id.* at 149. The trial judge enjoys broad discretion in determining whether the factors listed in *Daubert* reasonably measure reliability in a given case. *Id.* at 153. With this framework in mind, the Court turns to the issues surrounding the admissibility of Dr. Munzing's testimony.

In his motion, Defendant asks the Court to limit the expert testimony of Dr. Munzing, specifically his proposed testimony about the general prescribing practices of Defendants Babenco and Taylor and the general standard of care at LWC, arguing that his proposed testimony is unreliable and unfairly prejudicial to an extent that overshadows its probative value. At the motion hearing, the parties outlined the portions of Dr. Munzing's testimony on which they agreed[3] and highlighted the areas of disagreement. The parties agreed that Dr. Munzing could properly testify about the nine patient files he reviewed and give his opinion as to whether the prescriptions issued to those nine patients comported with professional practice and had a legitimate medical purpose.

[3] Defendant Naylor raised no objection to Dr. Munzing testifying about the "usual course of professional practice for physician assistants, nurses, and doctors, including the importance of offering correct treatment through individualized quality clinical care" or about "[a]ppropriate opioid prescribing practices, methods to monitor pain patients for indicators of drug abuse and/or diversion, and the signs of potential opioid addiction in patients" [Doc. 33 p. 3]. As stated above, to the extent that Defendant seeks to challenge Dr. Munzing's testimony based upon the Supreme Court's recent decision in *Ruan v. United States*, 142 S. Ct. 2370 (2022), she will do so in a motion *in limine*. The deadline for filing motions *in limine* is presently set for **October 24, 2022** [Doc. 72].

The parties also agreed that Dr. Munzing could not extrapolate from those nine patient files *alone* to the level of patient care at LWC. Beyond this, however, the parties diverged.

Defendant initially objected to additional expert testimony by Dr. Munzing on either (1) specific patients beyond the nine or (2) "profile testimony" derived from other information presented at trial. First, defense counsel argued that Dr. Munzing should not be permitted to give an expert opinion at trial regarding whether a specific patient's prescriptions comported with the professional standard of care based upon testimony either by the patient or by an employee. He argued that without reviewing that patient's file, Dr. Munzing would be providing an opinion that is not based in fact. Defense counsel also asserted that this procedure violated the notice requirements of Rule 16, because the defense would not know either the specific patient or patients who would be the subject of testimony at trial or Dr. Munzing's opinion on that patient or patients. Second, regarding Dr. Munzing's opinion on other data, such as prescribing data, defense counsel argued that this testimony on "red flags" also violates the notice requirements of Rule 16 and is tantamount to profile testimony, which invades the province of the jury. He argued that although the Government had disclosed this prescribing data in summary form, it had not disclosed Dr. Munzing's opinions on this data.

The Government argued that Dr. Munzing should be able to point out patterns either in the testimony regarding LWC patients or other data, such as prescribing data and/or from the Controlled Substance Monitoring Database ("CSMD"), that mirror patterns and the "red flags" in the nine patient files he reviewed. It argued Dr. Munzing can note these patterns without declaring any particular prescription to be issued outside the standard of care. With regard to notice, the Government stated that it had yet to decide which witnesses it would call at trial. AUSA Petro stated the Government would notify defense counsel of which patients would be at issue when the trial is closer. As to identifying patterns in the data, the Government asserted that Dr. Munzing

would not review the data before trial but would react to the testimony at trial based upon his knowledge and expertise and would testify whether patterns in the data were consistent with the nine files he reviewed in depth. It asserted that Defendant will be able to cross-examine the Government's witnesses and Dr. Munzing on this testimony. AUSA Petro asserted that Dr. Munzing's reaction to trial testimony—either on patients beyond the nine whose files he reviewed or on the CSMD or prescribing data—should be allowed in this case because Defendant is charged in a conspiracy, not just with the substantive counts of issuing illegitimate prescriptions.

With the Government's agreement to provide pretrial notice on other patients who would be the subject of its witnesses' testimony and potential reaction by Dr. Munzing, Mr. Kurtz responded that Defendant Naylor likely would not object to Dr. Munzing's reactions at trial to other patients exhibiting similar conduct as seen in the nine files but did object to Dr. Munzing testifying this was indicative of the practice as a whole. Mr. Kurtz argued that Dr. Munzing's proposed testimony from the prescribing and CSMD data is prejudicial and would potentially mislead the jury because he was testifying based upon numbers alone, without knowing the underlying information on patient care. He asserted that this proposed testimony (testimony on patterns in the data) was not probative because it was not based upon Dr. Munzing's review of files beyond the nine and is prejudicial because the Government would use this testimony to draw inferences to patient care at LWC.

AUSA Petro responded that an expert is permitted to educate the jury. She argued that Dr. Munzing's proposed testimony on patterns in the data is not making an ultimate conclusion about the standard of care of the entire practice.

A. "Ultimate Question" and "Profile" Testimony

At the hearing, the Government agreed that Dr. Munzing would not testify on whether LWC is a pill mill or give the "ultimate conclusion" that "the entire practice is bad." The Court

agrees such testimony is not permissible. First, the Court finds the Government does not propose to have Dr. Munzing testify about the characteristics of a pill mill but, instead, will have him testify about the standard of professional care and "[a]ppropriate opioid prescribing practices, methods to monitor pain patients for indicators of drug abuse and/or diversion, and the signs of potential opioid addiction in patients" [Doc. 33 p. 3]. A medical doctor's expertise on what constitutes legitimate medical practice "is not the same as expertise on how a criminal conspiracy typically runs. The doctor can say what is acceptable, medically, but he cannot say, by negative implication, what is typical for a pill mill." *United States v. Growder*, No. 6:17-CR-25-REW-HAI, 2019 WL 112307, *3 (E.D. Ky. Jan. 2, 2019).

Second, while law enforcement officers are typically permitted to provide expert testimony on the characteristics of a "pill mill," they may not testify as to whether the clinic at issue exhibits those characteristics. "A law enforcement expert's 'point by point examination of profile characteristics with specific reference' to the defendant, [creates] a particularly acute risk the jury will convict simply because the defendant fits the profile." *Stapleton*, 2013 WL 5966122, at *7 (quoting *United States v. Quigley*, 890 F.2d 1019, 2023 (8th Cir.), *cert. denied*, 493 U.S. 1091(1989)).

Excepting opinion on the defendant's intent, the opinion of an expert "is not objectionable just because it embraces an ultimate issue." Fed. Rule Evid. 704(a)-(b). "An expert may not opine on the overarching question of guilt or innocence[.]" *United States v. Volkman*, 797 F.3d 377, 388 (6th Cir. 2015). "When the rules speak of an expert's testimony embracing the ultimate issue, the reference must be to stating opinions that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue." *Berry*, 25 F.3d at 1353. In other words, while an expert may testify about a fact that relates to the ultimate issue, the expert may not give a legal conclusion. *Id.*

"Expert testimony on whether prescriptions are medically appropriate has long been the norm in controlled-substance prosecutions." *United States v. Lang*, 717 F. App'x 523, 534 (6th Cir. 2017) (holding that medical doctor properly gave opinion testimony on patient files that he reviewed). In *United States v. Volkman*, our appellate court held that the opinions of medical experts that prescriptions issued by the defendant physician had no legitimate medical purpose did not violate the province of the jury. 797 F.3d at 389-90; *see also United States v. Quinones*, 536 F. Supp. 2d 267, 274 (E.D.N.Y. 2008) (observing that to convict a medical professional of a violation of § 841(a)(1), the government must necessarily prove "what the medical profession would generally do in the circumstances"). The court also upheld the testimony by a medical doctor and a pharmacist on "the standard of care and the evaluation of certain drug combinations or quantities," determining that "both experts applied their understanding of the standard-of-care to a limited sample of facts." *Volkman*, 797 F.3d at 390. In *United States v. Hughes*, the medical expert responded to hypothetical questions by "offer[ing] his expert opinion that certain practices, established by other evidence, were beyond the scope of legitimate medical practice." 895 F.2d 1135, 1145 (6th Cir. 1990). However, the court pointed out that the expert "answered only hypothetical questions about medical practice." *Id.* at 1145 n.14.

Combining the reasoning in *Stapleton* on profile testimony with the cases permitting an expert to opine on the propriety of specific prescriptions, the undersigned finds that Dr. Munzing may not "extrapolate" from his opinions on certain prescriptions or aspects of patient care for the nine patients he reviewed at LWC to finding that the practice as a whole is illegitimate. *See Stapleton*, 2013 WL 5966122, at *7.

B. Testimony on Patterns in Data

The Court can evaluate the reliability of an expert in several ways. "Testimony can be reliable if it is 'based on sufficient facts or data,' or 'the product of reliable principles and

methods,' which the expert in turn has applied to the facts of the case." *Icare-EMS, Inc. v. Rural Metro Corp.*, No. 1:11–CV–45, 2012 WL 2343164, at *2 (E.D. Tenn. June 20, 2012) (citing Fed. R. Evid. 702) (Collier, D.J.); *see also In re Scrap Metal*, 527 F.3d at 528–29. Also, the reliability of expert testimony can be considered with respect to the critique by and/or acceptance of the relevant scientific community. *Icare-EMS*, 2012 WL 2343164, at *2. "*Daubert* provided a non-exclusive checklist for trial courts to consult in evaluating the reliability of expert testimony . . . includ[ing]: 'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community.'" *In re Scrap Metal*, 527 F.3d at 529 (quoting *United States v. Langan*, 263 F.3d 613, 621 (6th Cir. 2001)). The Court need not determine whether the proposed expert's testimony is correct but, instead, must "determine whether it rests upon a reliable foundation, as opposed to . . . unsupported speculation." *Id.* at 529–30.

Here, the Government asserts that based on Dr. Munzing's review of nine LWC patient files and his expertise as a medical doctor, he will testify about patterns in the prescribing data and CSMD data (which he has not reviewed before trial) that are the same as the patterns and the red flags in the nine patient files he reviewed. However, the Government fails to show that this is a reliable method for evaluating the prescribing or CSMD data. Indeed, other courts have questioned the reliability and fairness of such testimony.

In *United States v. Tran Trong Cuong* ("*Tran*"), the Fourth Circuit reversed a doctor's convictions of eighty counts of prescribing controlled substances without a legitimate medical purpose, that were based *solely* upon the medical expert's testimony that these prescriptions were consistent with a pattern of illegal prescribing in other patient files the expert examined. 18 F.3d 1132, 1141–43 (4th Cir. 1994).

> The government has convicted the appellant of 80 counts based upon the summary report of 33 patient files prepared and submitted by its medical expert and the testimony of the medical expert that the drug prescriptions contained in these files were made for other than legitimate medical purposes and beyond the bounds of medical practice. Although the witness admitted that he did not have sufficient information from some of the charts to conclude that the prescriptions were improper, these charts were included in the exhibit and also formed the basis of separate counts in the indictment, simply because they followed a pattern. This is not sufficient to convict a person of a felony, and it concerns us that, as to these 80 counts, defendant may have been found guilty of some counts by association—the association of the counts properly proved with those that were not.

Id. at 1141. The court distinguished the expert's "pattern" testimony from expert testimony on "red flags," observing that the former "tactic[]" (proof consisting only of copies of prescriptions and an expert's testimony on his summary of patient charts) "invite[s] a jury to find guilt by association or as a result of a pattern, and to conclude that if the physician violated the Controlled Substances Act in those counts supported by the testimony of patient-witnesses as to their personal contact and conversations with the defendant, then the defendant must be guilty of the remaining counts." *Id.* at 1142.

Relying on *Tran*, courts have rejected the sufficiency of "pattern" evidence when not supported by an expert's examination of the underlying patient files. *United States v. Rakhit*, No. 1:18-CR-33, 2021 WL 3375946, at *2 (N.D. Ohio Aug. 2, 2021) (excluding evidence of patient harm for patients outside the indictment due to "the potential for unfair prejudice and confusion . . . [and the] risk of convictions based on association, i.e., the jury would see a pattern of behavior and convict for individual counts that were not properly proved") (citing *Tran*, 18 F.3d at 1141); *United States v. Binder*, 26 F. Supp. 3d 656, 663 (E.D. Mich. 2014) (holding that when the government relies on "'pattern' or 'red flag' evidence sifted from a large number of patient files, particularly where no expert determination was made as to the suitability of the treatment in each

case, the evidence is insufficient, without more, to demonstrate guilt beyond a reasonable doubt") (citing *Tran*, 18 F.3d at 1141). *Compare United States v. Arny*, No. 12-cr-00011-JMH-EBA, 2017 WL 2831284, at *1–2 (E.D. Ky. June 29, 2017) (observing that opinions based on statistical data are suspect but admitted in healthcare fraud cases and reserving ruling on the admissibility of government's "opinion witness that [defendant] demonstrated a pattern of prescribing narcotics to patients over a prolonged period and at near-toxic or toxic doses" based on the large number of pills).

Other courts have distinguished *Tran* and found the expert's testimony admissible or the evidence sufficient because the expert reviewed the specific patient files. *United States v. Houdersheldt*, No. 3:19-00239, 2020 WL 7646808, at *10 (S.D.W.V. Dec. 23, 2020) (holding defendant's reliance on *Tran* to argue expert's methodology, consisting of review of patient files without personally examining the patient, is unreliable was "misplaced" because medical expert Dr. Timothy Munzing testified about red flags indicated in his review of the specific patient files); *United States v. Evans*, 892 F.3d 692, 705 (5th Cir. 2018) (observing that unlike in *Tran*, where the expert "testified he was relying on trends rather than specific patient files to find the prescriptions medically invalid," the expert reviewed the patient files and found they "contained inadequate documentation to justify the level of opioids prescribed"); *United States v. Bourlier*, 518 F. App'x 848, 852 (11th Cir. 2013) (distinguishing *Tran*, because the medical expert "specifically discussed the medical file of each patient charged in the indictment, including those who did not testify, commented on the prescriptions they received, and made individual assessments about their treatment"). These cases suggest that the pattern testimony sought by the Government would be based on insufficient data because Dr. Munzing will only have reviewed a small fraction of the patient files underlying the general prescribing or CSMD data.

In its response, the Government cites to two cases that permitted a medical expert to testify about the defendant physician's legitimate medical purpose for issuing the prescriptions charged based upon the expert's review of patient records *and* prescribing data: *United States v. Martinez*, 588 F.3d 301 (6th Cir. 2009) (health care fraud) and *United States v. Wells*, 211 F.3d 988 (6th Cir. 2000). In *Martinez*,

> The Government's expert witness, Dr. Douglas Kennedy, a pain-management specialist, reviewed the videos of office visits and the medical records for the patients named in the indictment. He testified that Martinez's billing to health care benefit programs was "not appropriate in any fashion," (Joint Appendix ("JA") 1359), because the procedures and office visits for which Martinez submitted bills "could not have been performed." (JA 1359.) Moreover, even if the procedures were performed, "they were not medically necessary in any way." (JA 1359.) Dr. Kennedy further explained that the appropriate medical practice for administering nerve-block injections allows for no more than "three injections over three to six months" unless additional injections are "absolutely indicated and everything else has been ruled out," (JA 1303, 1305), but that Martinez routinely provided as many as twenty injections to patients at their weekly or biweekly appointments. Additionally, Dr. Kennedy concluded that Martinez's prescriptions for controlled substances could not have been for legitimate medical purposes and that such prescriptions were outside the bounds of accepted medical practice. . . . .
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> . . . . And another government expert witness, Dr. Theodore Parran, a specialist in pain management and in the treatment of addiction, reviewed the files for those patients named in the indictment and testified that Martinez prescribed medication for patients he saw for only a few minutes and frequently ignored "red flags" indicating that a patient's drug use "was out of control." (JA 2084–91, 2134–66.)

588 F.3d at 307–08. While the medical experts were permitted to testify about the propriety of the defendant's prescribing practices, the analysis does not indicate that they testified beyond the patient files they reviewed, i.e., the patients named in the indictment.

Similarly, in *Wells*, the government's medical expert was permitted to testify regarding whether the defendant physician's prescriptions for the single patient named and also charged in

the indictment were outside the scope of medical practice and not for any legitimate medical purpose:

> In addition [to the medical expert's report], the government provided defense counsel with documents reviewed by [the expert] that showed the prescriptions [the defendant] had written for [the patient]'s use, and a brief letter written by [the expert] in January 1998 which stated that [the expert] had reviewed both the [defendant]'s file on [the patient] and the prescriptions written or ordered via telephone in [the patient]'s name. The letter clearly stated the ultimate point of [the expert]'s testimony: "it is my opinion that the prescriptions as to each of the counts in the indictment are outside the scope of the professional practice and not for a legitimate medical purpose."

211 F.3d at 997 (finding the government complied with the notice requirements of Fed. R. Crim. P. 16 in disclosing the expert's report and other materials). Thus, the medical expert reviewed the prescribing records relating to the patient, whose file the expert had reviewed, and then determined whether the prescriptions *for that patient* were medically necessary. There is no indication that the expert testified regarding patterns in the prescribing data for other patients.

The Court finds that the medical experts in *Marinez* and *Wells* testified similarly to Dr. Munzing's proposed testimony on the nine patient files he reviewed. As stated above, Defendant Naylor does not challenge this proposed testimony. Based upon the information before it, the Court finds the Government has not shown the reliability of Dr. Munzing's proposed testimony on patterns in the data by a preponderance of the evidence. As the gatekeeper for expert testimony, the Court finds that the proposed expert testimony on patterns in the prescribing and CSMD data must be halted at the gate.

C. Notice

Defendant Naylor also objected to the lack of notice inherent in its proposed testimony by Dr. Munzing on the propriety of prescriptions for specific patients and on alleged patterns in the evidence. Defendant argues that because the Government is not required to disclose a witness list,

the defense would have no way to prepare for expert testimony about any one of the over 1400 patients who could be discussed or testify at trial.

Federal Rule of Criminal Procedure 16(a)(1)(G) requires the government to provide a written summary of the expert testimony it intends to use in its case-in-chief at trial. This summary "must describe the witness's opinions, the bases and reasons for those opinions, and the witness's qualifications." Fed. R. Crim. P. 16(a)(1)(G). An amendment to Rule 16(a)(1)(G), set to take effect on December 1, 2022, states that expert disclosures must be made "sufficiently before trial to provide a fair opportunity for the defendant to meet the government's evidence." The advisory committee notes to the proposed amendment to Rule 16(a)(1)(G) observe that "[s]ometimes a party may need to secure its own expert to respond to expert testimony disclosed by the other party." Fed. R. Crim. P. 16(a)(1)(G) advisory committee's note to 2022 amendment. Here, the Court finds that permitting the Government to present Dr. Munzing with the prescribing and CSMD data—data which it already possesses and has disclosed to Defendant—for the first time at trial and then seek his expert opinion about patterns in the data would deprive Defendant of a fair opportunity to meet that opinion.

As to testimony on other LWC patients, the Government asserts that it has yet to decide which witnesses it will call at trial. At the motion hearing, AUSA Petro stated the Government will notify defense counsel which patients will be at issue when the trial is closer. The Court **ORDERS** that the Government disclose to the Defendant *any patients* about which Dr. Munzing may provide an expert opinion no later than **four weeks** before trial.

III. CONCLUSION

For the reasons set forth above, Defendant's Motion to Limit Expert Medical Opinion [**Doc. 60**] is **GRANTED in part** as follows:

(1) Dr. Munzing may provide expert testimony about the medical necessity of prescriptions of the nine patients whose files he reviewed and about other patients, whose files or care are the subject of trial testimony, so long as those additional patients are disclosed to Defendant **four weeks** before trial;

(2) As agreed by the parties, Dr. Munzing may not extrapolate from the nine patient files he reviewed to the general patient care or prescribing practices of LWC or its medical staff; and

(3) Dr. Munzing may not opine on patterns in the prescribing data or the CSMD data because the Government has failed to show that such testimony is reliable.

IT IS SO ORDERED.

ENTER:

Debra C. Poplin
United States Magistrate Judge